



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

06/03

18 December 2002

INITIAL ASSESSMENT REPORT

APPLICATION A481

FOOD FROM GLUFOSINATE AMMONIUM -TOLERANT SOYBEAN EVENTS A2704-12 AND A5547-127

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:

29 January 2003

(See “Invitation for Public Submissions” for details)

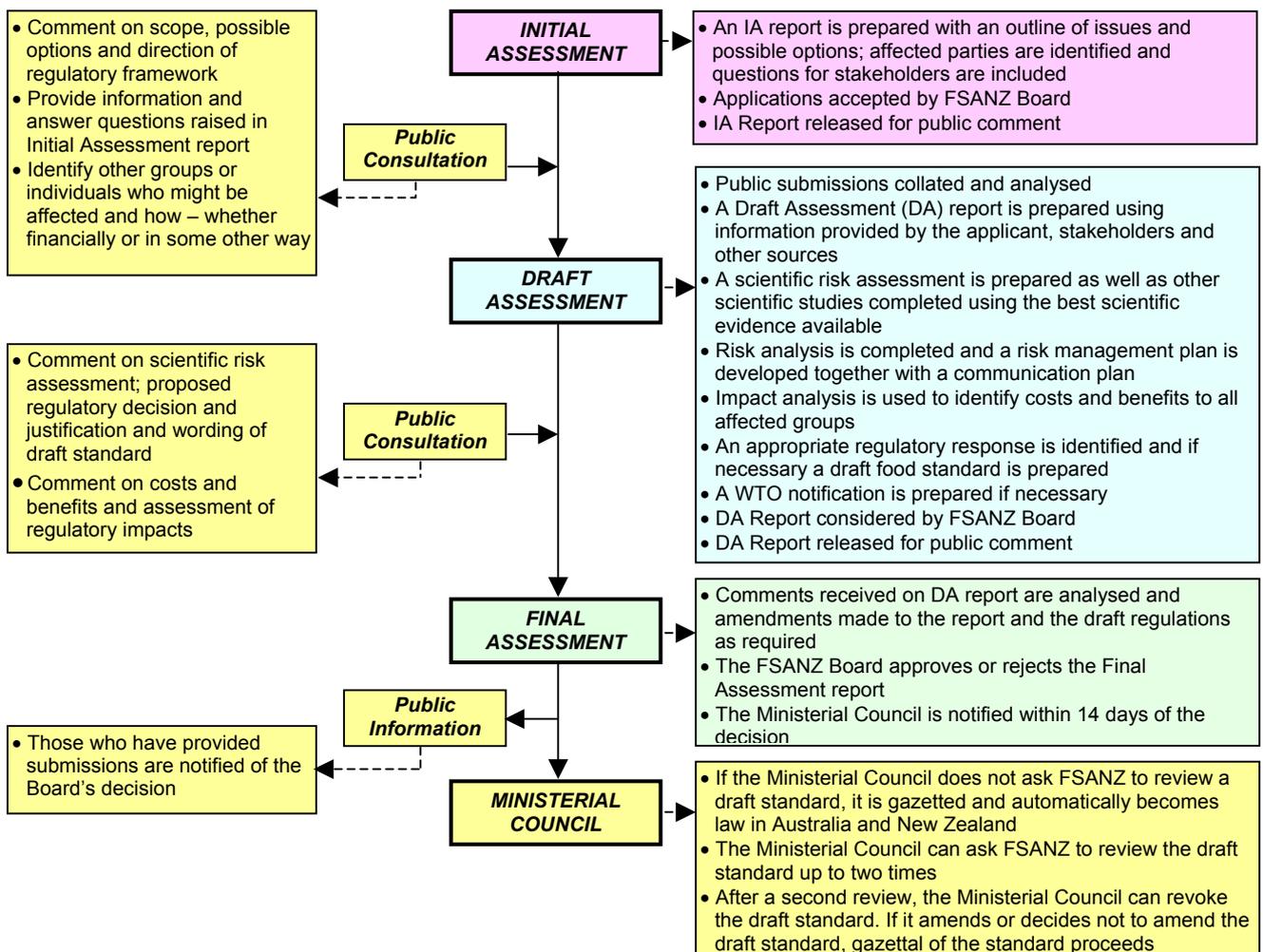
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A481, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (Code) from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word "Submission" and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by the Authority **by 29 January 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

An application has been received from Monsanto Australia Limited to amend the *Australia New Zealand Food Standards Code* (the *Food Standards Code*) to approve food derived from genetically modified (GM) herbicide tolerant soybeans, called A2704-12 and A5547-127 soybeans. Standard 1.5.2 – Food Produced using Gene Technology requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

This Initial Assessment report is not an assessment of the merits of the application but rather is an assessment of whether the application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the Act). It has been concluded that the application fulfils the requirements for Initial Assessment as prescribed in the Act. The application has therefore been accepted for further assessment.

The purpose of this report is to provide relevant information supplied by the applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the application, now that it has been accepted. The information needed to complete the assessment will include information received from public submissions.

There is currently no approval for the sale and use of food from A2704-12 and A5547-127 soybeans. If this application is successful, FSANZ will amend the Food Standards Code and insert a permission to use food from A2704-12 and A5547-127 soybeans in the Table to clause 2 of Standard 1.5.2.

A2704-12 and A5547-127 soybeans have been genetically modified for tolerance to glufosinate ammonium herbicides. Tolerance to the herbicides is achieved by expression in the plant of a bacterially derived enzyme that specifically inactivates the herbicide, thus allowing the plants to survive and grow following applications of the herbicide. A2704-12 and A5547-127 soybeans also contain a new gene encoding resistance to the antibiotics ampicillin and penicillin – this gene is not however active in the plant.

The glufosinate ammonium-tolerant soybeans have been developed for cultivation in the major soybean growing regions of the world and, at present, are not intended for cultivation in either Australia or New Zealand. Food derived from A2704-12 and A5547-127 soybeans may however still enter the food supply in Australia and New Zealand via imported products.

Public submissions are now invited on this Initial Assessment report. Comments are specifically requested on the scientific aspects of this application, in particular, information relevant to the safety assessment of food from A2704-12 and A5547-127 soybeans.

1. Introduction

An application was received from Bayer CropScience Pty Ltd on 13 November 2002 seeking approval for food derived from glufosinate ammonium-tolerant soybean transformation events A2704-12 and A5547-127 (referred to herein as A2704-12 and A5547-127 soybeans) under Standard 1.5.2 Food Produced Using Gene Technology in the *Australia New Zealand Food Standards Code* (the *Food Standards Code*).

The genetic modification to the soybeans involved the transfer of the following bacterial genes:

- a synthetic *pat* gene (based on the native *pat* gene from the soil bacterium *Streptomyces viridochromogenes*), which codes for the enzyme phosphinothricin acetyltransferase (PAT), conferring tolerance to glufosinate-ammonium herbicides; and
- the *bla* gene (derived from *Escherichia coli*) which codes for the enzyme β -lactamase and confers resistance to β -lactam antibiotics.

An Initial Assessment of the application has been completed and public comment is now being sought to assist in the Draft Assessment of the application.

2. Regulatory Problem

Standard 1.5.2 requires that a genetically modified (GM) food undergo a pre-market safety assessment before it may be sold in Australia and New Zealand. Foods that have been assessed under the Standard, once fully approved, are listed in the Table to clause 2 of the Standard.

Bayer CropSciences Pty Ltd has developed a new variety of herbicide-tolerant soybean primarily for agronomic purposes. Before food derived from this event can enter the food supply in Australia and New Zealand, it must first be assessed for safety and an amendment to the *Food Standards Code* must be approved by the FSANZ Board, and subsequently be notified to the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the *Food Standards Code* may only be gazetted, once the Ministerial Council process has been finalised.

Bayer CropSciences Pty Ltd has therefore applied to have Standard 1.5.2 amended to include food derived from A2704-12 and A5547-127 soybeans.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in Section 10 of the *Food Standards Australia New Zealand Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and

- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

In addressing the issue of approving the sale and use of food from A2704-12 and A5547-127 soybeans, the key objectives are the protection of public health and safety and the provision of adequate information to consumers. In fulfilling these objectives, FSANZ will also have regard for the need for standards to be based on risk analysis using the best available scientific evidence and the desirability of an efficient and internationally competitive food industry.

4. Background

A2704-12 and A5547-127 soybeans have been genetically modified to be tolerant to glufosinate ammonium containing herbicides through the expression of the PAT enzyme. Glufosinate ammonium is the active constituent in a range of herbicides with the following commercial names: Basta®, Finale®, Buster®, Harvest® and Liberty®. Glufosinate ammonium is currently registered in Australia under the name of Basta® for non-selective uses, or Finale® for turf and home garden uses, and as Buster® in New Zealand.

PAT acetylates glufosinate ammonium to an inactive form thus enabling the plant to survive and grow in the presence of the herbicide. The PAT enzyme expressed in the soybeans is encoded by a synthetic *pat* gene, which shares about 70% homology at the DNA level with the native *pat* gene from *S. viridochromogenes*. The amino acid sequence of the synthetic *pat* gene is however identical to that of the native gene, hence the PAT enzyme expressed in the soybeans is also identical to that derived from the native gene.

A2704-12 and A5547-127 soybeans will be used in conventional breeding programs to produce glufosinate ammonium-tolerant soybean varieties which will be sold commercially under the brand name LibertyLink® soybeans.

Glufosinate ammonium is a non-selective, contact herbicide that provides effective post-emergence control of many broadleaf and grassy weeds. The mode of action of the herbicide is to inhibit the enzyme glutamine synthetase, an essential enzyme involved with ammonia accumulation and nitrogen metabolism in plants. The effects of this inhibition result in an over accumulation of ammonia in the plant which leads to cell death. The production of PAT by the soybeans enables the use of glufosinate ammonium herbicides post-emergence without risk of damaging the crop. The applicant has stated that development of genetically modified glufosinate ammonium-tolerant soybeans will provide a selective use for glufosinate ammonium, creating a valuable new weed management tool for soybean producers.

The A2704-12 and A5547-127 soybeans also contain a non-functional copy of the *bla* gene, which encodes resistance to some β -lactam antibiotics, such as penicillin and ampicillin.

The *bla* gene was used as a marker to select transformed bacteria from non-transformed bacteria during the DNA cloning and recombination steps undertaken in the laboratory prior to transformation of the plant cells. The *bla* gene was disrupted to render it non-functional prior to plant cell transformation.

The soybeans have been developed for cultivation in the major soybean producing countries of the world. The applicant has indicated that at present they have no plans to develop glufosinate ammonium-tolerant soybeans for cropping in either Australia or New Zealand. Food from A2704-12 and A5547-127 soybeans will therefore be entering the Australian and New Zealand food supply as imported, processed, food products only. There are three major food products derived from soybeans – seeds, oil and meal. Whole soybeans¹ are used to produce soy sprouts, baked soybeans, roasted soybeans, full fat soy flour and the traditional soy foods such as miso, tofu, soy sauce and soymilk. Soybean oil has many food uses including in cooking oils, mayonnaise, margarine, salad dressings, sandwich spreads, and shortenings. Soybeans are also processed into lecithin, an emulsifying agent (food additive) found in a wide variety of foods. Finished food products containing soybean ingredients therefore include beer, noodles, breads, flours, sausage casings, pastries, crackers, meat substitutes, milk substitutes and confectionery.

Soybean varieties containing events A2704-12 and A5547-127 have been cleared for food use in the United States, Canada, Japan, South Africa (A2704-12 only) and Russia. Applications have also been submitted to the relevant authorities in the European Union, China, Taiwan, Mexico, Argentina, South Africa (A5547-127) and Singapore.

5. Relevant Issues

5.1 Safety assessment of food from A2704-12 and A5547-127 soybeans

Food from A2704-12 and A5547-127 soybeans will be evaluated according to the safety assessment guidelines prepared by FSANZ². The safety assessment will include the following:

- a characterisation of the genetic modification to the plant;
- a consideration of the safety of any transferred antibiotic resistance genes;
- characterisation of any novel proteins, including their potential toxicity and allergenicity;
- a comparative analysis of the key constituents of A2704-12 and A5547-127 soybeans as well as their nutritional impact.

The applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of events A2704-12 and A5547-127,

¹ At present there is no approval to import whole viable glufosinate ammonium-tolerant soybean seeds into either Australia or New Zealand. This would require separate approvals from the Office of the Gene Technology Regulatory in Australia and the Environmental Risk Management Authority in New Zealand.

² FSANZ (2001) Information for Applicants – Amending Standard A18/Standard 1.5.2 – Food Produced Using Gene Technology.

the toxicity and potential allergenicity of PAT, compositional analyses of food derived from A2704-12 and A5547-127 soybeans, and animal feeding studies to demonstrate the nutritional adequacy of the food. In addition to information supplied by the applicant, FSANZ will also have regard to other available information, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community.

5.2 Labelling

Under Standard 1.5.2, GM food must be labelled if novel DNA and/or protein are present in the final food and also where the food has altered characteristics.

The applicant has indicated that novel DNA and/or protein are likely to be present in some of the less-refined food fractions of soybeans. This suggests that a number of food products containing ingredients derived from A2704-12 and A5547-127 soybeans will require labelling, should food from A2704-12 and A5547-127 soybeans be approved.

6. Regulatory Options

Option 1 – prohibit food from glufosinate ammonium-tolerant soybean events A2704-12 and A5547-127

Maintain the *status quo* by not amending the *Food Standards Code* to approve the sale of food derived from A2704-12 and A5547-127 soybeans.

Option 2 – approve food from glufosinate ammonium-tolerant soybean events A2704-12 and A5547-127

Amend the *Food Standards Code* to permit the sale and use of food derived from A2704-12 and A5547-127 soybeans, with or without listing special conditions in the Table to clause 2 of Standard 1.5.2.

7. Impact Analysis

7.1 Affected parties

- Consumers, particularly those who have concerns about biotechnology;
- Food importers and distributors of wholesale ingredients;
- The manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations and enforcement agencies in particular who will need to ensure that any approved products are correctly labelled.

The cultivation of soybeans containing events A2704-12 and A5547-127 may have an impact (either positive or negative) on primary producers and the environment. At present, the glufosinate ammonium-tolerant soybeans are intended for cultivation in the major soybean growing regions around the world and the applicant does not intend to develop them for cultivation in either Australia or New Zealand. Should the applicant wish to grow glufosinate

ammonium-tolerant soybeans in Australia and/or New Zealand in the future, a comprehensive environmental risk analysis would be required by various government agencies such as the Office of the Gene Technology regulator (OGTR), the National Registration Authority (NRA) and Environment Australia (EA), in addition to the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Fisheries (MAF) in New Zealand.

7.2 Impact analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

The following is an initial assessment by FSANZ of the costs and benefits of the two regulatory options identified so far. This is based on information supplied by the applicant and experience FSANZ has gained from consideration of previous applications relating to GM foods. Your comments are also invited on the costs and benefits identified for the options below.

Option 1

Consumers: Cost in terms of a possible reduction in the availability of certain food products.

Cost associated with higher retail prices for segregated foods.

No impact on consumers wishing to avoid GM foods, as food from A2704-12 and A5547-127 soybeans is not currently permitted in the food supply.

Government: No immediate impact.

Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.

Industry: Cost in terms of restricting innovation in food/crop production for both growers and other sectors of the food industry. Cost to the food industry to source either segregated or non-GM supplies.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry.

Option 2

Consumers: Benefit of lower prices, to the extent that savings from production efficiencies are passed on.

Benefit of access to a greater range of products including imported food products containing ingredients derived from A2704-12 and A5547-127 soybeans.

Cost to consumers wishing to avoid GM food by a potential restriction of choice of products, or increased prices for non-GM food.

Government: No direct impact.

This decision is unlikely to impact on monitoring resources.

Industry: Benefit to growers in lower production costs and reduced exposure to agricultural chemicals used to manage insect pests and weeds.

Benefit to importers and distributors of overseas food products as the product range is extended.

Benefit for food manufacturers in that the choice of raw ingredients is extended.

Benefit to food retailers in an increased product range.

To further develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

8. Consultation

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further FSANZ documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of FANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this application. Comments that would be useful could cover:

- Scientific aspects of this application, in particular, information relevant to the safety assessment of food from A2704-12 and A5547-127 soybeans;
- Parties that might be affected by having this application approved or rejected;
- Arguments in support or opposition to permitting food from A2704-12 and A5547-127 soybeans; and
- Potential costs and benefits to consumers, industry and government.

9. Conclusion and Recommendation

This application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*.

Accordingly, FSANZ has decided to accept the application and will now undertake a Draft Assessment and prepare a Draft Assessment Report.

11. Implementation and review

This information will be provided once the Draft Assessment has been completed.